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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/909,414	07/19/2001	Frank L. Graham	AdVec10CA	7286
29847	7590	06/02/2005	EXAMINER	
BEUSSE BROWNLEE WOLTER MORA & MAIRE			VOGEL, NANCY S	
390 N. ORANGE AVENUE			ART UNIT	
SUITE 2500			PAPER NUMBER	
ORLANDO, FL 32801			1636	

DATE MAILED: 06/02/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/909,414	Applicant(s) GRAHAM ET AL.	
	Examiner Nancy T. Vogel	Art Unit 1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 March 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-21 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-21 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

AS

DETAILED ACTION

Claims 1-21 are pending in the case

Response to Amendment

Any rejection of record in the previous action not addressed in this office action is withdrawn.

Claim Rejections - 35 USC § 102

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3 and 5-21 are rejected under 35 U.S.C. 102(b) as being anticipated by Kaleko (WO/97/25446).

This rejection is maintained essentially for the reasons made of record in the previous Office action, mailed 8/12/03, in slightly modified form, as necessitated by applicant's amendments to the claims filed 3/15/04.

Kaleko teaches a method for making an infectious adenovirus which comprises contacting a cell with, or introducing into a cell, a first nucleic acid sequence, containing adenovirus sequences insufficient to encode an infectious adenovirus, comprising at least one site-specific recombinase recognition target site which is recognized by a site-specific recombinase, (see page 5, line 32 – page 6, line 5), and a second nucleic acid sequence encoding adenovirus sequences which, in the absence of adenoviral

replication factors provided in trans or intermolecular recombination with said first nucleic acid sequence, are insufficient to encode an infectious adenovirus, and additionally comprising a recombinase recognition target site, whereby said first and said second nucleic acid sequences, in combination and following site specific intermolecular recombination, result in production of an infectious adenovirus (see page 6, line 6-31). The site-specific recombinase which recognizes said site-specific recombinase recognition target sites may be expressed by a cell into which said first and said second nucleic acids are introduced such as 293 cells, on a third nucleic acid (see page 7, lines 16-21), or on the first or second nucleic acid (page 10, lines 13-15). The reference discloses an embodiment in which the first nucleic acid is a plasmid which contains adenovirus sequences insufficient to encode an infectious, replicable or package able adenovirus, comprising the 5' ITR, packaging signal, a heterologous DNA and a recombinase target 3' of the heterologous DNA (page 8 lines 3-28). The first nucleic acid may be deleted for adenovirus protein encoding genes (page 11-13). The recombinase recognition site may be lox or frt, and the recombinase may be Cre or Flp (pages 10-11). The reference discloses kits comprising said nucleic acids.

Applicant's arguments filed 11/14/03 have been considered but have not been found convincing.

Applicant has argued that Kaleko disclose that the second polynucleotide includes at least one adenoviral ITR which includes a terminal protein bound to the ITR, and further, that the reference repeatedly states the association of terminal protein with an ITR of a polynucleotide construct that is involved in the generation of an adenoviral

vector" (page 10 of the response). Applicant states that "no claim of the present invention comprises a terminal protein attached to or associated with an ITR on either of the nucleic acid sequences". However, it is maintained that the language of the instant claims does not exclude the presence of such elements as a terminal protein attached to or associated with an ITR. There is no language in the instant claims reciting that a terminal protein is not attached to an ITR, and the claim language is open. Therefore, the rejection is maintained.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kaleko (WO/97/25446) cited above, in view of Bett et al. (Proc. Natl. Acad. Sci. USA 91:8802-8806 (1994)).

This rejection is maintained for reasons of record set forth in the previous Office action, mailed 8/12/03.

Applicant's arguments filed 11/14/03 have been considered but have not been found convincing.

Applicant has argued that since Kaleko teaches "the use of terminal protein", it teaches away from the present invention, and therefore, the combination with any reference does not achieve the present invention (page 11 of the response). However,

for the reasons set forth above, applicant's arguments are not found convincing regarding the Kaleko reference, and therefore the rejection is maintained.

The following is a new rejection:

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1, 7, 11 and 13 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-12 of U.S. Patent No. 6,379,943. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the instant application are generic to (fully encompass) the claims in the conflicting patent. The claims of the instant application recite methods for making an infectious adenovirus comprising contacting a cell with or introducing into a cell first and second nucleic acid molecules which are generic to the specific first and second nucleic acid sequences recited in the

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patent claims. Therefore, the instant claims are anticipated by the claims of the conflicting patent.

Declaration

The Declaration from Dr. Frank Graham under 37 CFR 1.132 filed 11/14/03 has been considered and entered into the file. This Declaration was apparently not filed in response to any outstanding rejection.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nancy T. Vogel whose telephone number is (571) 272-0780. The examiner can normally be reached on 7:00 - 3:30, Monday - Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Irem Yucel, Ph.D. can be reached on (571) 272-0781. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


TERRY MCKELVEY
PRIMARY EXAMINER